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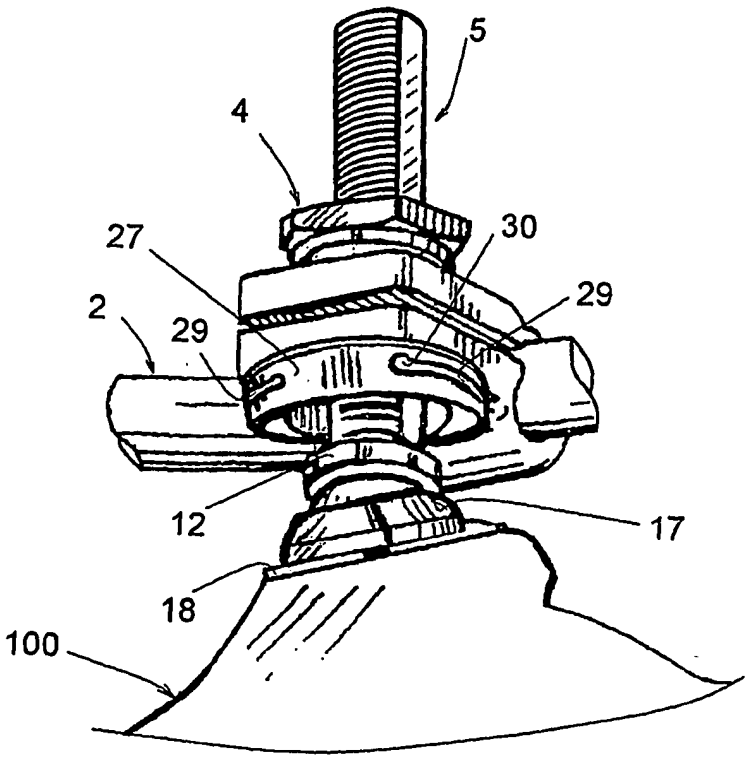
(54) Title: VERTEBRAL OSTEOSYNTHESIS EQUIPMENT



(57) Abstract: This equipment includes bony anchoring members, one or two linking rods (2) and parts (3) for connecting this(these) rod(s) (2) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud (5) articulated with respect to a base portion (6) ; clamping means (4) enable assembly of the connecting part (3) on the anchoring member. According to the invention, the proximal stud (5) comprises a surface (12, 32) forming an axial stop, against which the connecting part (3) to be installed on the polyaxial anchoring member is intended for resting, and said clamping means (4) enable to clamp this connecting part (3) against this surface (12, 32), said surface (12, 32) being positioned so that the connecting part (3), when it is clamped against this surface (12, 32), is not clamped against the base portion (6) so that there remains, after clamping, a possibility of articulated backlash of the proximal stud (5) with respect to said base portion (6).

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VERTEBRAL OSTEOSYNTHESIS EQUIPMENT

This patent application claims the priorities to :

- FR 03 07776, filed on June 27, 2003 ;
- US Provisional application N° 60/490,519, filed on July 29, 2003 ;
- FR 04 00747, filed on January 27, 2004 ;
- FR 04 03413, filed on April 1st, 2004.

The present invention relates to a vertebral osteosynthesis equipment.

A vertebral osteosynthesis equipment generally includes bony anchoring members, such as pedicular screws and/or hooks, one or two linking rods, intended to be connected to these anchoring members and to be attached to the vertebrae by dint thereof, and parts for connecting this(these) linking rod(s) to these anchoring members. The equipment may also comprise length-adjustable crossbeams, which link transversally two parallel linking rods in order to hold said rods with respect to one another.

In an existing type of equipment, at least one anchoring member is "polyaxial", i.e. comprises a base portion enabling bony anchoring thereof and a proximal threaded stud, articulated with respect to that base portion, whereon a nut may be screwed. Each connecting part may comprise a rounded section intended for surrounding a linking rod and two parallel drilled wings, these wings being intended for engaging onto said proximal threaded stud and for being clamped, by means of that nut, against a bearing surface provided on the base portion, said operation enabling to clamp said rounded section around the linking rod and thereby ensuring longitudinal immobilisation of this rod with respect to the anchoring member.

The existing vertebral osteosynthesis equipment is designed for immobilising two vertebrae with respect to one another, for eliminating any relative movement of these vertebrae, liable to be painful, or to restore the adequate position of a vertebra with respect to the other. To provide such immobilisation, such equipment is designed for ensuring perfectly rigid assembly of the linking rods with the anchoring members.

Such rigid assembly may however not prove desirable in all cases. It leads in particular to significant loads being exerted at anchoring bony zones of said anchoring members, as well as to increased loads at the vertebral

articulations situated on both sides of the vertebral segment(s) treated, which may lead to precocious degenerescences of these articulations.

It is known by the document US 5,735,851 to provide a polyaxial anchoring member whereof the proximal threaded stud may accommodate one or several concave spacers screwed thereon, these spacers being intended for resting against the convex head of the base portion of the anchoring member. The function of these spacers, besides adjusting the height of the connecting part, is to generate an additional clamping load on the head of the base portion in order to enhance the immobilisation of the stud with respect to that base portion after clamping.

The anchoring member according to this prior document realises consequently a rigid assembly of the stud with respect to the base portion, which does not enable to remedy the shortcomings aforementioned.

The document FR 2 697 742 describes a monoaxial anchoring member including a washer made of shock-absorbing material placed between a bearing surface formed by the base portion and the connecting part. The clamping nut immobilises however this connecting part with respect to the proximal threaded stud of the anchoring member, and said washer only enables very limited movements of the connecting part with respect to the anchoring member.

The equipment according to this prior document also realises consequently a rigid or quasi-rigid assembly which does not enable to remedy the shortcomings aforementioned.

The purpose of the present invention is precisely to remedy these shortcomings.

The equipment affected comprises, in itself, bony anchoring members, such as pedicular screws and/or hooks, one or two linking rods, intended to be connected to these anchoring members, and parts for connecting this(these) rod(s) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud articulated with respect to a base portion enabling bony anchoring ; clamping means enable assembly of the connecting part on the anchoring member.

According to the invention, the proximal stud comprises a surface forming an axial stop, against which the connecting part to be installed on the polyaxial anchoring member is intended for resting, and said clamping means enable to clamp this connecting part against this surface, said surface being positioned so that the connecting part, when it is clamped against this surface, is not clamped against the base portion so that there remains, after clamping, a possibility of articulated backlash of the proximal stud with respect to said base portion.

Thus, in the equipment according to the invention, said connecting part is not immobilised with respect to the anchoring member but may move slightly, relative thereto, in order to allow limited movements of the vertebrae. The stresses exerted on the anchoring bony zones of the anchoring member are thus notably reduced, as well as the risks of over-stresses at the vertebral articulations situated on both sides of the vertebral segment treated.

Preferably, at least one polyaxial anchoring member comprises at least one part or portion of a part with elastically deformable structure, interposed, after assembly, between said connecting part and a bearing surface.

This part or portion of a part with elastically deformable structure enables to dampen the movement of the connecting part, and hence of the linking rod, with respect to said base portion. Thanks to the axial stop surface shown by the stud, the clamping of the connecting part is carried out independent of any clamping of said part or portion of a part, which is elastically deformable, and hence does not interfere therewith.

Said part or portion of a part with elastically deformable structure may be formed in order to dampen the movement of the proximal stud over the whole backlash of this stud, notably if it is composed of a compressible material, or may be formed to provide this dampening effect only in the extreme positions of such backlash.

According to a possible embodiment of the invention in the latter case, said part or portion of a part with elastically deformable structure is composed of a circular wall attached to the connecting part, this wall including at least one transversal slot running therethrough, provided on one side of this wall according to a direction substantially perpendicular to that occupied by a

linking rod when this rod is engaged in the connecting part, this slot enabling to reduce the thickness of this circular wall when a load is exerted on this wall in the axial direction, on the side where the slot is.

The proximal stud and said surface forming an axial stop may be formed in order to enable the adjustment of the axial position of this surface with respect to the proximal stud, and this surface may be formed to clamp said part or portion of a part with elastically deformable structure between said surface and said bearing surface against which this part or portion of a part rests.

Said surface forming an axial stop enables then, according to the clamping performed, to adjust the dampening effect produced by said part or portion of a part with elastically deformable structure.

According to an embodiment of the invention in such a case, the proximal stud is threaded and said surface forming an axial stop is in the form of a part with a tapered hole which may be screwed on this stud.

Said bearing surface against which the part or portion of a part with elastically deformable structure rests, may be a surface provided on said base portion or the vertebral bone itself.

The walls of the proximal stud and of the anchoring member which slip against one another during the backlash of this stud may include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

When the articulation of this proximal stud consists of faces in the form of a sphere or of portions of a sphere slipping against one another, advantageously, these faces exhibit a diameter which is significantly greater than that of the proximal stud, notably at least double the diameter of this stud, in order to increase the contact surface of its faces with one another.

The frictions are thus exerted on enlarged surfaces, thereby reducing the risk of wear of said faces.

Besides, at least one linking rod of the equipment may comprise :

- a portion of rod including a part with elastically deformable structure and an articulated stud,

- another portion of rod including a bearing zone against this part with elastically deformable structure, and

- clamping means to clamp this bearing zone against this part with elastically deformable structure.

The connecting part comprises preferably a rounded section intended for surrounding a linking rod and two parallel drilled wings, intended for engaging onto said proximal stud and for being clamped towards one another in order to provide the clamping of said rounded section around a linking rod.

The invention will be better understood, and other characteristics and advantages thereof will appear, with reference to the appended schematic drawing, representing, for non-limiting exemplification purposes, two embodiments of parts included in the equipment affected.

Figure 1 is one of these parts, before assembly, according to an embodiment ;

Figure 2 is a view of these parts similar to Figure 1, after assembly ;

Figure 3 is a view of these parts similar to Figure 2, according to a direction perpendicular to that according to this figure 2, in a first position ;

Figure 4 is a view of these parts similar to Figure 3, in a second position ;

Figure 5 is a view of these parts similar to Figure 3, in a third position ;

Figure 6 is a perspective view of the same parts, after placing the screw in a vertebra and before final clamping ;

Figure 7 is a view of these parts similar to Figure 6, after final clamping ;

Figure 8 is a view of said parts, before assembly, according to the second embodiment ;

Figure 9 is a view of said parts similar to Figure 8, after assembly ;

Figure 10 is a partial sectional view of a linking rod, before assembly, and

Figure 11 is a view similar to Figure 10, after assembly.

Figure 1 represents a polyaxial pedicular screw 1, a rod 2 linking several of these screws 1, a part 3 connecting this rod 2 to one of these screws 1 and a nut 4 enabling to assemble the linking rod 2 to this screw 1.

The screw 1 comprises a proximal threaded stud 5 and a threaded base portion 6. The stud 5 is intended for receiving the part 3 engaged thereon and

the nut 4 screwed thereon while the body 6 is intended for insertion in the pedicula 100 of a vertebra, as shown on Figures 6 and 7.

The stud 5 exhibits a threaded cylindrical portion 10, an enlarged distal head 11 and a collar 12 forming a stopping surface.

The portion 10 exhibits a zone 15 of reduced diameter, enabling to break its proximal portion after placing and clamping the nut 4, as appears by comparison of Figures 2 and 3.

The head 11 exhibits a diameter double the diameter of the portion 10 and looks like a spherical cap. This head 11 is intended for engaging in a proximal cavity 16 delineated by the proximal zone of the body 6 and for retention in this cavity 16 by crimping a proximal wall 17 exhibited by this body 6. After crimping, the wall 17 is shaped in order to show a hemispherical proximal form. As shown on Figure 1, the dimensions of the cavity 16 and of the aperture delineated by the wall 17 after crimping to let through the stud 5 are such that a multidirectional backlash of this stud 5 with respect to the body 6 is possible.

The body 6 also comprises a proximal collar 18, intended for abutting against the pedicula 100. This collar 18 exhibits several radial notches 19, notably four notches at 90° to one another, for holding the body 6 in rotation when clamping the nut 4.

The linking rod 2 is cylindrical and exhibits such rigidity as to hold several vertebrae with respect to one another. This rod 2 is however deformable in order to be shaped relative to the correction of the rachis to be performed.

The connecting part 3 comprises a rounded section 20 intended for surrounding the linking rod 2 and two parallel lateral wings 21 drilled with holes for engaging the part 3 on the stud 5. These wings 21 are distant mutually so that, in a distant position, the rod 2 may be inserted and may slide in the portion 20, and that, in a close position provided by the clamping of the nut 4, they clamp the portion 20 around the rod 2, immobilising the latter with respect to the part 3.

As shown on Figures 1 and 2, the proximal wing 21 exhibits a proximal pan 25 whereof the shape is suitable for the nut 4 to rest on, while the distal

wing 21 comprises a circular cavity 26 enabling the engagement of this wing on the collar 12.

This distal wing 21 comprises moreover a circular wall 27 integral therewith. The height of this wall 27 is smaller than that of the wall 17, and delineates an internal concave spherical face 28 of greater diameter than that of this wall 17.

Moreover, two transversal slots 29 are provided in this wall 27, on two opposite sides of the wall 27, and according to a direction substantially perpendicular to that occupied by the linking rod 2 when this rod is engaged in the rounded section 20. Each slot 29 extends angularly over approximately 120° of the wall 27 and terminated by a widened zone 30 in the form of a circle.

As can be understood with reference to Figure 5, the distal portions of the wall 27 delineated by the slots 29 have, at these rounded zones 30, reduced height, so that these portions may flex at these zones 30, enabling thereby reduction in height of the wall 27.

In practice, the number of screws 1 necessary to the treatment to be performed is placed in the pediculae 100 of the vertebrae affected, then the connecting parts 3, with the rod 2 engaged in the portions 20, are placed on the studs 5, until engagement of the collars 12 in the cavities 26. The nuts 4 are then clamped to immobilise the rod 2 with respect to the parts 3 and the proximal portions of the studs 5 are cut off.

In this clamping position of each part 3 against the corresponding collar 12, the wall 27 only rests against the wall 17 by a very small surface, as shown on Figure 2. This clamping preserves the possibility of articulated backlash of the proximal stud 5 with respect to the body of screw 6, this backlash being free as long as the wall 27 has not abutted against the body 6 (cf. figure 4) then being possible with a deformation of the wall 27 beyond, thereby dampening the movement of the stud 5 in the maximal angles of backlash of this stud (cf. figure 5). The possible limit of the backlash of the latter corresponds to the contact of the edges of the wall 27 delineating the slots 29.

Thanks to the diameter of its face 28, greater than the diameter of the wall 17, the wall 27 does not oppose the backlash of the stud 5.

The slipping zones of the head 11 against the wall 17 and of the face 28 against the wall 17 may include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

Figures 8 and 9 represent parts 2 to 4 identical or similar to those described with reference to Figures 1 and 2, the parts proving identical or similar being designated by the same numeric references.

In this case, the part 3 is deprived of the wall 27, and the equipment comprises, for at least one anchoring member 1, a part 31 in the form of a washer made of material with elastically deformable structure, notably silicon or PMMA, and a washer 32, notably metallic, with a tapered bore to be screwed on the stud 5 until the part 31 is clamped between said washer and the portion 6 of the screw.

The part 31 delineates a cavity as a portion of a sphere, of dimensions adjusted to the external face of the wall 17.

The washer 32 comprises an upper portion adjusted to the cavity 26 and a lower widened portion, including a peripheral rim which may be engaged on the upper portion of the washer 31, as shown on Figure 9.

This washer 32 may be screwed on the stud 5 until the part 31 is clamped relative to a given dampening effect requested for the backlash of the stud 5. Once such clamping has been provided, the part 3, with the rod 2 engaged therein, is placed on the stud 5, then the nut 4 is clamped to immobilise the rod 2 with respect to the part 3.

Figures 10 and 11 show a linking rod 2 of the equipment which comprises :

- a portion of rod 2a including a part 41 with elastically deformable structure and a articulated threaded stud 5, this articulation being identical to that described previously,

- another portion of rod 2b, including a bearing zone 42 against this part 41 and a tapered bore 43 for screwing this portion 2b on the stud 5 in order to clamp the bearing zone 42 against the part 41.

The linking rod 2 may thus also present a certain degree of elastic flexibility.

As shown by the foregoing, the invention provides a vertebral osteosynthesis equipment enabling certain clearance of the connecting part 3, and therefore of the linking rod 2, with respect to the base anchoring portion 6 to the vertebra, to allow limited movements of the vertebrae treated. The stresses exerted on the anchoring bony zones of the anchoring member are thus notably reduced, as well as the risks of over-stresses at vertebral articulations situated on both sides of the vertebral segment treated.

It is obvious that the invention is not limited to the embodiment described above for exemplification purposes but it extends to all the embodiments covered by the claims appended therein. Consequently, one would not depart from the framework of the invention by replacing the wall 27 with a washer of elastic material or with an elastic structure, for instance in the form of a spring.

CLAIMS

1 – Vertebral osteosynthesis equipment, including bony anchoring members, such as pedicular screws (1) and/or hooks, one or two linking rods (2), intended to be connected to these anchoring members, and parts (3) for connecting this(these) rod(s) (2) to these anchoring members ; at least one of the anchoring members is of the "polyaxial" type, i.e. it comprises a proximal stud (5) articulated with respect to a base portion (6) enabling bony anchoring ; clamping means (4) enable assembly of the connecting part (3) on the anchoring member ;

equipment characterized in that the proximal stud (5) comprises a surface (12, 32) forming an axial stop, against which the connecting part (3) to be installed on the polyaxial anchoring member is intended for resting, and in that said clamping means (4) enable to clamp this connecting part (3) against this surface (12, 32), said surface (12, 32) being positioned so that the connecting part (3), when it is clamped against this surface (12, 32), is not clamped against the base portion (6) so that there remains, after clamping, a possibility of articulated backlash of the proximal stud (5) with respect to said base portion (6).

2 – Vertebral osteosynthesis equipment according to claim 1, characterized in that at least one polyaxial anchoring member comprises at least one part or portion of a part (31) with elastically deformable structure, interposed, after assembly, between said connecting part (3) and a bearing surface (17, 18).

3 – Vertebral osteosynthesis equipment according to claim 2, characterized in that said part or portion of a part (31) with elastically deformable structure is formed in order to dampen the movement of the proximal stud (5) over the whole backlash of this stud, and is notably composed of a compressible material.

4 – Vertebral osteosynthesis equipment according to claim 2, characterized in that said part or portion of a part (31) with elastically deformable structure is formed in order to provide this dampening effect only in the extreme positions of the backlash of the proximal stud (5).

5 – Vertebral osteosynthesis equipment according to any of claims 1 to 4, characterized in that the proximal stud (5) and said surface (12, 32) forming an axial stop are formed in order to enable the adjustment of the axial position of this surface (12, 32) with respect to the proximal stud (5), and in that this surface (12, 32) is formed to clamp said part or portion of a part (31) with elastically deformable structure between said surface (12, 32) and said bearing surface (17, 18) against which this part or portion of a part rests.

6 – Vertebral osteosynthesis equipment according to claim 5, characterized in that the proximal stud (5) is threaded and said surface (32) forming an axial stop is in the form of a part with a tapered hole which may be screwed on this stud (5).

7 – Vertebral osteosynthesis equipment according to any of claims 2 to 6, characterized in that said bearing surface (17, 18) against which the part or portion of a part (31) with elastically deformable structure rests, may be a surface (17, 18) provided on said base portion (6) or the vertebral bone itself.

8 – Vertebral osteosynthesis equipment according to any of claims 1 to 7, characterized in that the walls (11, 17) of the proximal stud (5) and of the base portion (6) which slip against one another during the backlash of this stud (5) include a smooth and resistant coating layer, capable of resisting a very large number of slipping movements of these walls against one another, such as a ceramic or titanium nitride coating layer.

9 – Vertebral osteosynthesis equipment according to any of claims 1 to 8, characterized in that the articulation of the proximal stud (5) consists of faces (11, 17) in the form of a sphere or of portions of a sphere slipping against one another, and in that these faces (11, 17) exhibit a diameter which is significantly greater than that of the proximal stud (5), notably at least double the diameter of this stud.

10 – Vertebral osteosynthesis equipment according to any of claims 1 to 9, characterized in that at least one linking rod (2) of the equipment comprises :

- a portion (2a) of rod including a part (41) with elastically deformable structure and an articulated stud (5),

- another portion (2b) of rod including a bearing zone (42) against this part (41) with elastically deformable structure, and

- clamping means (43) to clamp this bearing zone (42) against this part (41) with elastically deformable structure.

11 – Vertebral osteosynthesis equipment according to any of claims 1 to 10, characterized in that the connecting part (3) comprises preferably a rounded section (20) intended for surrounding a linking rod (2) and two parallel drilled wings (21), intended for engaging onto said proximal stud (5) and for being clamped towards one another in order to provide the clamping of said rounded section (20) around a linking rod (2).

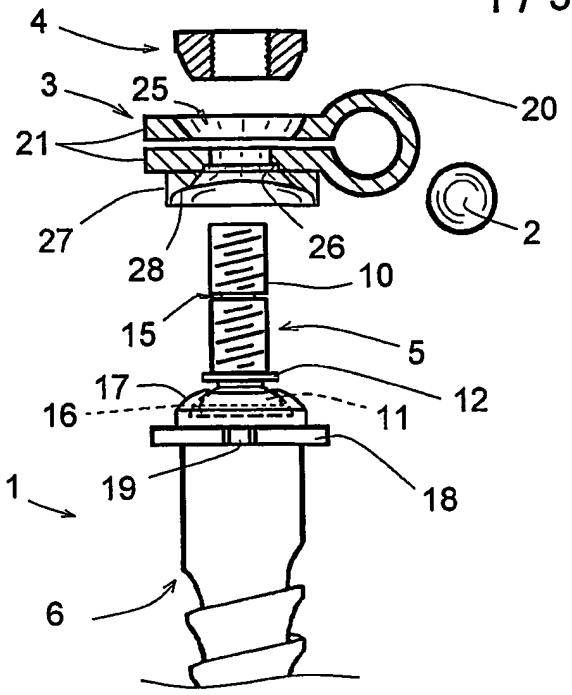


FIG. 1

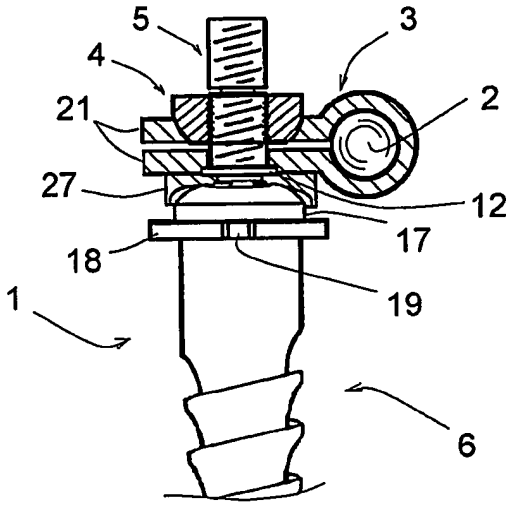


FIG. 2

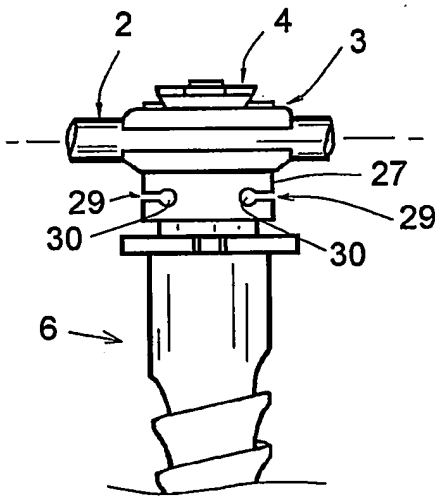


FIG. 3

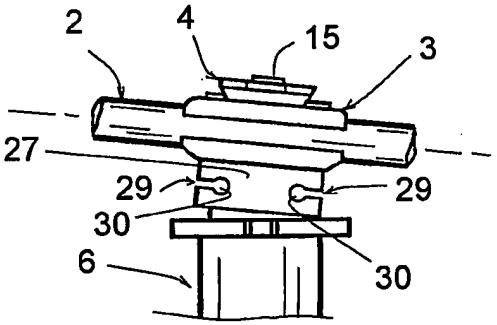


FIG. 4

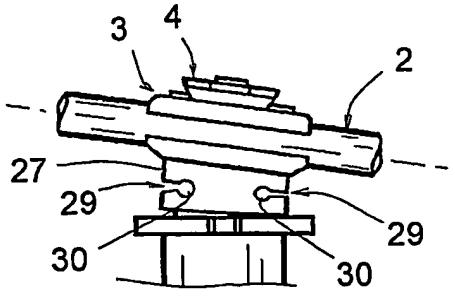


FIG. 5

FIG. 6

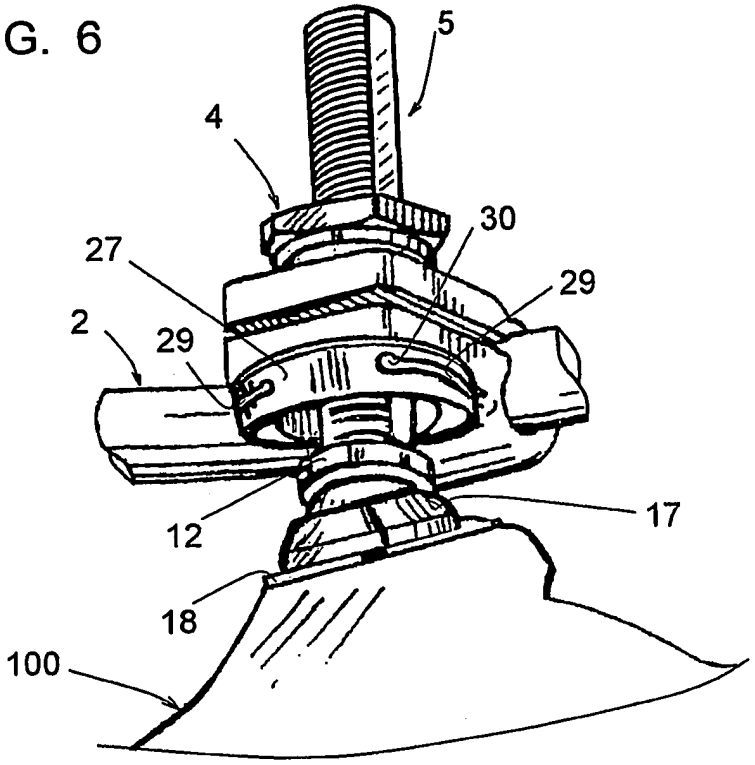
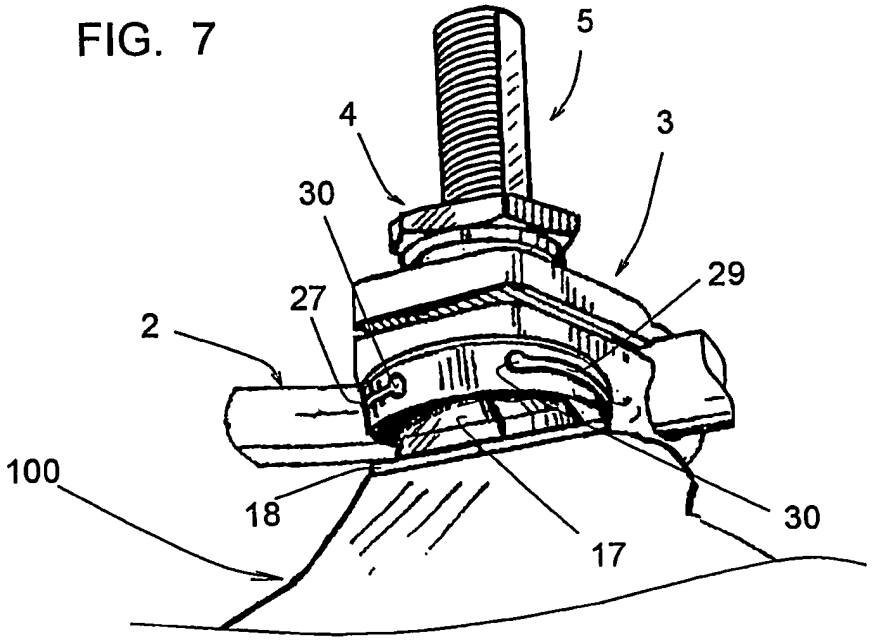
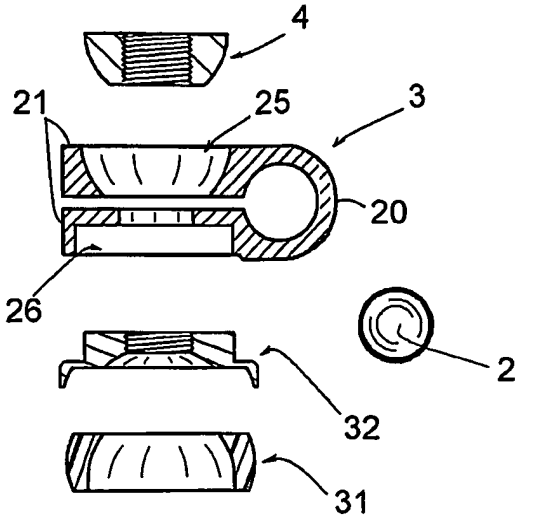


FIG. 7





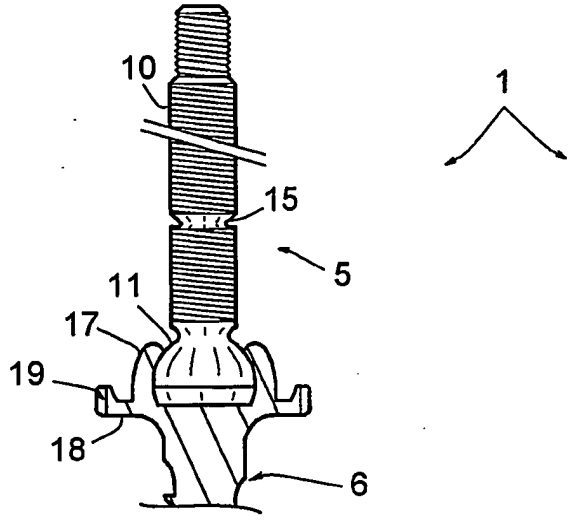


FIG. 8

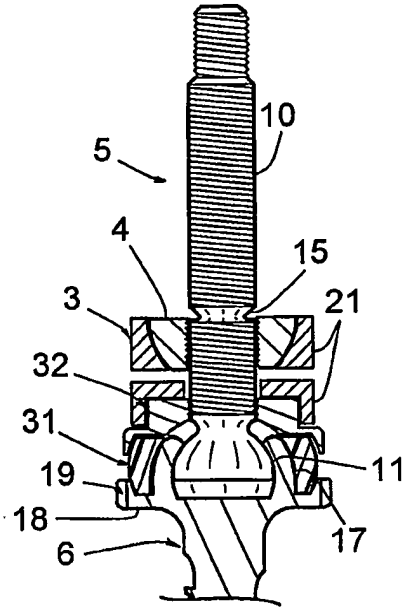


FIG. 9

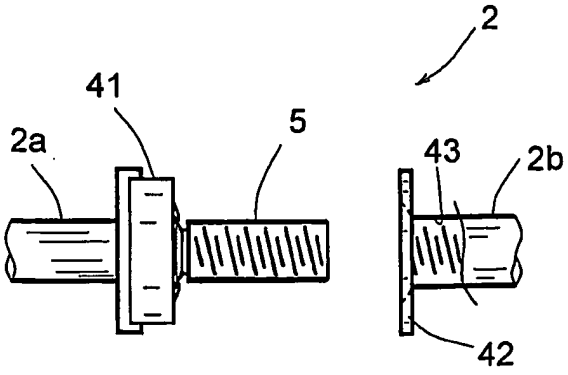


FIG. 10

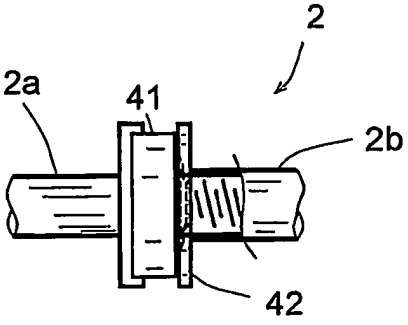


FIG. 11

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/IB2004/002463

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/55038 A (TAYLOR J.) 10 December 1998 (1998-12-10) figures 1-3	1
A	US 5 735 851 A (ERRICO J.P.ET AL) 7 April 1998 (1998-04-07) cited in the application figure 10a	1
A	FR 2 697 742 A (BIOMAT) 13 May 1994 (1994-05-13) cited in the application page 11, line 14 - page 12, line 9; figure 1	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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4 November 2004	15/11/2004

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INTERNATIONAL SEARCH REPORT

International Application No
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